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09/813,225	03/20/2001	Joseph A. Orr	4637US	3421

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TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER

MALLARI, PATRICIA C

ART UNIT PAPER NUMBER

3736

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

58

Office Action Summary	Application No. 09/813,225	Applicant(s) ORR ET AL.	
	Examiner Patricia C. Mallari	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-70 and 72-120 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 100-109 is/are allowed.
- 6) ☒ Claim(s) 34-42, 44, 45, 47, 52-60, 63, 64, 70, 72-74, 76, 77, 79, 84, 88-94, 110 and 112-115 is/are rejected.
- 7) ☒ Claim(s) 43, 46, 48-51, 61, 62, 65-69, 75, 78, 80-83, 85-87, 95-99 and 116-120 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections made under 35 U.S.C. 102 in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34-42, 44, 45, 47, 52-60, 63, 64, 70, 72-74, 76, 77, 79, 84, 88-94, 110, 112-115 are rejected under 35 U.S.C. 102(e) as anticipated by US Patent No. 6,200,271 to Kück et al. The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Kück discloses a method for noninvasively estimating at least one of a pulmonary capillary blood flow and a cardiac output of a patient comprising a step of evaluating respiration of the patient during a first ventilation state, and a step of evaluating respiration of the patient during a second ventilation state having a duration of about 18 to about 60 seconds (col. 9, lines 24-52; figs. 4 and 5). The length of the duration of the "before" ventilation state is disclosed, for example, as being 6 seconds (Col. 9, lines 40-

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43) or 50 seconds, wherein 6 seconds is considered to be about 18 seconds and 50 seconds is considered to be about 42 seconds, particularly in reference to a time period, such as a day. The length of the duration of the “during” ventilation state is disclosed as being, for example, 50 seconds (col. 9, lines 44-52 of Kück) or 60 seconds (figs. 4 and 5), wherein 50 seconds is considered similarly to be about 42 seconds and 60 seconds is considered to be about 42 seconds.

Regarding claim 35, the step of evaluating respiration of the patient during the first ventilation state is conducted immediately before evaluating respiration of the patient during the second ventilation state (figs. 4-5).

Regarding claim 36, the step of evaluating the patient during another first ventilation state is repeated immediately following the evaluation of respiration during the second ventilation state (col. 9, lines 52-60; figs. 4-5).

Regarding claims 37, 38, and 72, the evaluation of either of the first or second ventilation states is effected for about 30 seconds as shown in the graphs of figures 4 and 5. Note that time duration in this case, and in claims 39-41, 70, 71, 73, 74, 76, 77, and 79, the time duration cited refers to the time during which the patient’s respiration is evaluated, rather than the duration of the ventilation state itself, as in claim 34.

Regarding claims 39, 40, 73, and 74, the evaluation of the patient’s respiration during either of the first and second ventilation states is effected for a duration of at least about 30% of a combine duration of evaluating respiration of the patient during both the first and the second ventilation states, wherein figures 4 and 5 show that evaluation of respiration during the “before” state occurs for roughly 50 seconds,

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evaluation of the respiration during the “during” state occurs for roughly 60 seconds. In either case, the duration of the evaluation is at least about 30% of the combined duration of both evaluations.

Regarding claims 41 and 76, the respiration evaluation during the first and second ventilation states are effected for a combined duration of at most about two minutes (figs. 4 and 5).

Regarding claim 42, the first ventilation state comprises the patient rebreathing (col. 9, lines 44-53), wherein the “during” phase disclosed by Kück may be either the first or the second ventilation state as claimed in claim 42.

Regarding claim 44, the first ventilation state comprises the patient breathing air (col. 9, lines 32-60), where Kück shows that any gas mixture breathed by the patient constitutes “air” (col. 8, lines 51-52).

Regarding claims 47, 52-60, 63, 64, 84, 88-94, 110, and 112-115, the step of evaluating respiration of the patient is effected before calculating pulmonary capillary blood flow or cardiac output of the patient (fig. 3; col. 10, lines 45-65).

Regarding claims 52-60, 63, 64, 84, 88-94, 110, and 112-115, Kück discloses an “after” phase which constitutes the “another first ventilation state” in claim 52 of the instant application. The “after” phase of Kück has a duration of about 18 seconds to about 42 seconds, wherein figures 4-5 of Kück show the duration of the “after” phase to be about 30 seconds, and wherein the applicants describe it as lasting for 40 seconds (see p. 22 of the applicants’ arguments filed 1/10/05).

With further regard to claims 53, 54, the evaluation of respiration during each of the first, second, and another first ventilation state is effected for substantially the same duration, according to the applicants description of "substantially a same duration" on p. 12, paragraph 0048 of the instant specification. Figures 4 and 5 of Kück show the duration of the evaluation during the "before" state as being roughly 50 seconds, during the "during" state as being roughly 60 seconds, and during the "after" state as being roughly 40 seconds. Note that the time limitation in this case, and in claims 55-60 and 112, differs from the limitation in claims 52 and 110, where the time duration refers to the duration of the first, second, or another ventilation state itself, rather than to the length of time during which the patient is evaluated.

With further regard to claims 55-57, the evaluation of respiration during each of the first, second, and another first ventilation states is effected for about 30 seconds, wherein the values of 40, 50, and 60 seconds are each "about 30 seconds", particularly in reference to, for example, the duration of a day.

With further regard to claims 58 and 59, the duration of the evaluation of respiration of each of the first and second ventilation states is effected for at least about 30% of a combined duration of the first and second ventilation states (figs. 4 and 5), where 50 seconds and 60 seconds each constitute at least 30% of a combined duration of 50 seconds with 60 seconds.

With further regard to claim 60, the evaluation of respiration of the patient during the first and second ventilation states are effected for a combined duration of at most 2 minutes (figs. 4 and 5).

With further regard to claim 63, the first ventilation state comprises the patient breathing air (col. 9, lines 32-60), where Kück shows that any gas mixture breathed by the patient constitutes "air" (col. 8, lines 51-52).

With further regard to claims 70-74, 76, 77, and 79, Kück discloses a first phase in which a change in the effective ventilation of a patient is induced, wherein this first phase is the time that the patient's respiration is evaluated in the "during" state of Kück, and a second phase during which a change in the effective ventilation of the patient is not present, wherein the time that the patient's respiration is evaluated in either the "before" or "after" state of Kück is this second phase (col. 9, lines 24-60). Figures 4 and 5 show these phases to have substantially the same duration according to the applicants' description of substantially the same duration on p.12, paragraph 0048 of the instant specification. Also, it is assumed that Kück, because the reference discloses a first phase in which a change in effective ventilation is induced (col. 2, lines 43-57) and a second phase during which a change in the ventilation is not present (col. 2, lines 40-43), discloses a differential Fick technique as claimed. If the inclusion of the claimed steps alone does not constitute a Fick technique as claimed by the present application, then the claim fails to include matter critical or essential to the practice of the invention (i.e. a problem under 35 U.S.C. 112, 1st paragraph).

With further regard to claim 77, the first phase comprises a rebreathing phase ("during" col. 9, lines 43-53) and the second phase comprises a non-rebreathing phase ("before" or "after" col. 9, lines 31-43 and lines 53-60).

With further regard to claim 79, the second phase occurs before the first phase (col. 9, lines 31-52).

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34, 35, 37-42, 44, 45, 47, 70, 72-74, 76, 77, and 79 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent No. 6,106,480 to Gama De Abreu et al. Gama De Abreu teaches a method of determining cardiac output or pulmonary capillary blood flow (col. 2, lines 21-23; col. 4, line 54-col. 5, line 5) comprising a step of evaluating respiration of a patient during a first ventilation state having a duration between 18 and 42 seconds, wherein a duration of 60 seconds is about 42 seconds, and evaluating respiration of the patient during a second ventilation state having a duration between 18 and 42 seconds (col. 2, lines 40-57). With regard to the duration of the first ventilation state, it is noted that a duration of 60 seconds is about 42 seconds, particularly in comparison to, for example, the duration of a day.

Alternatively, the applicants have not disclosed that the particular range of between 18 and 42 seconds solves any stated problem or is for any particular purpose. Moreover, it appears that the method of Gama De Abreu or the applicants' invention would perform equally well with either a duration between 18 and 42 seconds or a

duration of 60 seconds. In fact, the applicants disclose the range of 18 to 42 seconds as just an example of a suitable duration of either of the ventilation states (paragraph 48 of the instant application), and the specification further states that the duration of the first ventilation state may be equal to, as little as 30% of, or as much as 70% of the duration of the second ventilation state (paragraph 48 of the instant application). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to use a duration of between 18 and 42 seconds as the duration of the first ventilation step in the method of Gama de Abreu because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Gama de Abreu.

Regarding claims 35, 75, figures 3 and 4 show the change between the first ventilation state and the second ventilation state as being immediate.

Regarding claims 37 and 38, the step of evaluating respiration of the patient during the first ventilation state and/or the second ventilation state is effected for about 30 seconds (col. 2, lines 40-54), wherein the ventilation state disclosed by Gama de Abreu et al. on col. 2, lines 52-54 could be either the first or the second ventilation state as stated by the instant claim.

Regarding claims 39 and 40, the step of evaluating respiration of the patient during the first ventilation state or during the second ventilation state is effected for a duration of at least about 30% of a combined duration of evaluating respiration of the patient during both the first and second ventilation states (col. 2, lines 40-54; fig. 4), wherein a period of approximately 30 seconds or a period of between 18 and 42

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seconds is at least about 30% of a duration of approximately 30 seconds combined with between 18 and 42 seconds). Similarly, a period of 60 seconds is at least about 30% of a duration of 30 seconds combined with 60 seconds. Also the ventilation state disclosed by Gama de Abreu et al. on col. 2, lines 52-54 could be either the first or the second ventilation state as stated by the instant claim.

Regarding claim 41, the step of evaluating respiration during the first ventilation state and the step of evaluating respiration during the second ventilation state are effected for a combined duration of at most about two minutes (fig. 4; col. 2, lines 40-54), wherein a duration of 30 seconds and a duration of between 18 and 42 seconds, or a duration of 30 seconds and a duration of 60 seconds combine to produce a total duration of less than two minutes.

Regarding claim 42, the step of evaluating respiration of the patient during the first ventilation state comprises evaluating respiration during rebreathing (col. 2, lines 52-54).

Regarding claim 44, the step of evaluating respiration of the patient during the second ventilation state comprises evaluating respiration of the patient while the patient is breathing air (col. 2, lines 40-51).

Regarding claim 45, the step of evaluating respiration of the patient during the second ventilation state comprises evaluating respiration of the patient while the patient is breathing gas or a gas mixture comprising at least a concentration of oxygen present in air (col. 2, lines 40-50), wherein air contains at least a concentration of oxygen (see "air", *The American Heritage* ® *Concise Dictionary*).

Regarding claim 47, the step of evaluating respiration of the patient during eth second ventilation state is effected before calculating the pulmonary capillary blood flow of the patient (col. 4, lines 54-col. 5, line 7).

Response to Arguments

Applicant's arguments filed 1/10/05 have been fully considered but they are not persuasive.

With regard to claims 35, 37-42, 44, 45, and 47, the applicants argue that Gama De Abreu does not expressly or inherently describe first and second ventilation states that both have duration of about 18 to about 42 seconds. In response to this argument, the applicants should refer to the rejection set forth above under 35 U.S.C. 102/103 where it is explained how Gama De Abreu does describe two ventilation states each having a duration of about 18 to about 42 second and, in the alternative, how such a duration would have been obvious to one of ordinary skill in the art. The applicants similarly contend that Kück lacks any express or inherent description of a method which includes evaluating duration first and second ventilation states that each last for about 18 seconds to about 42 seconds. The applicants should also refer to the rejection set forth about under 35 U.S.C. 102(e) as to how Kück does disclose such a method.

Regarding claim 36, the applicants state that Kück does not teach an immediate repetition of evaluating respiration of a subject during another first ventilation. However, Kück, in figures 4 and 5 and lines 52-60 of column 9, fail to show any intervening state between the "during" and the "after" states. Kück describes that "after re-breathing, two-way valve 68 is repositioned to prevent the flow of gases through deadspace 70 as the

patient breathes” (col. 9, lines 52-54 of Kück), and figures 4 and 5 show the “after” phase to immediately follow the “during” phase.

Regarding claim 45, the applicants maintain that Kück does not teach evaluating respiration of a subject during a second ventilation state in which the subject breathes gas or a gas mixture comprising at least a concentration of oxygen present in air. The applicants should note that the language of claim 45, which is dependent upon claim 34, does not require that the second state follow the first state in time. Kück discloses a method in which the patient breathes gas mixtures, wherein the gas mixture may be air (col. 8, lines 50-51 of Kück). Air, by definition (see “air”, *American Heritage® Concise Dictionary*), contains at least a concentration of oxygen. Therefore, the patient breathes a gas mixture comprising at least a concentration of oxygen present in air, at least during the “before” and “after” phases described by Kück.

The applicants state that Kück does not expressly or inherently describe a differential Fick technique that includes two phases of substantially the same duration, but fail to point out what steps or elements the method of Kück lacks. The applicants should again refer to the rejection set forth above under 35 U.S.C. 102(e) of claim 70 as being anticipated by Kück as to how Kück does indeed teach a differential Fick technique as claimed.

Regarding claim 72, the applicants contend that Kück fails to teach both phases having durations of about thirty seconds. However, as stated above, the durations disclosed figures 4 and 5 of Kück show the first two phases to have substantially the same duration according to the applicants’ description of substantially the same

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duration on p.12, paragraph 0048 of the instant specification, wherein the applicants state:

The first and second phases, or ventilation states, of the inventive differential Fick technique may be effected for substantially the same amount of time, meaning that, while the first and second phases may have exactly the same duration, as depicted in FIG. 9B, one of the phases may alternatively be somewhat longer than the other. Either the first phase or the second phase of the differential Fick technique of the present invention may comprise as little as about 30% of the combined duration of the first and second phases or as much as about 70% of the combined duration of the first and second phases.

Clearly a first ventilation state lasting 50 seconds and a second ventilation state of 60 seconds constitute ventilation states being effected for substantially the same amount of time, where the first and second phases may either have exactly the same duration or one may be longer than the other, as stated by the applicants.

Regarding the rejection under 35 U.S.C. 103(a) of claim 43 as being unpatentable over Gama De Abreu in view of US Patent No. 6,540,689 to Orr et al. and the rejection of claim 75 as being unpatentable over Kück in view of Orr et al., the applicants have stated that the instant application (application no. 09/813,225) and the Orr et al. patent were both, at the time the invention of the instant application was made, owned by NTC Technology, Inc. and therefore the Orr et al. patent does not constitute prior art under 35 U.S.C. 103 (p. 20 of the applicants' arguments filed 1/10/05).

Regarding the rejection of 52-60, 63, 64, 84, 88-94, 110, and 112-115 under 35 U.S.C. 103 as being unpatentable over US Patent No. 6,200,271 to Kück, and the rejection of claim 75 as being unpatentable over Kück in view of Orr et al., the applicants have stated that the instant application (application no. 09/813,225) and the Kück patent were both, at the time the invention of the instant application was made,

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owned by NTC Technology, Inc. and therefore the Kück patent does not constitute prior art under 35 U.S.C. 103 (p.20 of the applicants' arguments filed 1/10/05).

Allowable Subject Matter

Claims 100-109 are allowed. Claims 43, 46, 48-51, 61, 62, 65-69, 75,78, 80-83, 85-87, 95-99, 111, and 116-120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The allowability of claims 46, 48-51, 61, 62, 65-69, 78, 80-83, 85-87, 95-109, 111, and 116-120 were addressed in a previous Office action filed 3/4/04.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 43, the prior art of record fails to teach or fairly suggest a method for non-invasively estimating at least one of pulmonary capillary blood flow and a cardiac output of a subject, wherein evaluating respiration of the subject during the first ventilation state comprises employing a best-fit line method of rebreathing, in combination with all of the other limitations of the claim.

Regarding claim 75, the prior art of record fails to teach or fairly suggest a differential Fick technique, wherein the first and second phases are repeated in immediate sequence with one another, in combination with all of the other limitations of the claim.

Conclusion

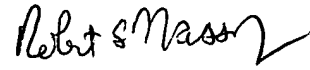
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patricia Mallari
Patent Examiner
Art Unit 3736


ROBERT L. NASSAR
PRIMARY EXAMINER